

We claim:

1. An endoprosthesis assembly comprising an implantable endoprosthesis capable of being diametrically expanded from a smaller diameter to a larger diameter; and a generally tubular, delicate constraining sheath provided coaxially around the endoprosthesis at the smaller diameter of the endoprosthesis, said constraining sheath being provided with means for disruption initiated by application of a distending force to the constraining sheath, wherein said assembly is contained within a packaging sheath which is not required to be implantable.

10 2. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 21 hours.

15 3. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 24 hours.

20 4. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 48 hours.

25 5. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 5 days.

30 6. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 10 days.

35 7. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 20 days.

8. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an

increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 30 days.

9. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 45 days.

10. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 60 days.

11. An endoprosthesis assembly according to claim 1 wherein the endoprosthesis is a self-expanding endoprosthesis.

12. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 21 hours.

13. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 24 hours.

14. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 48 hours.

25. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 5 days.

30. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 10 days.

35. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 20 days.

18. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 30 days.

5 19. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 45 days.

10 20. An endoprosthesis assembly according to claim 11 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 60 days.

21. An endoprosthesis assembly according to claim 1 wherein the delicate constraining sheath comprises porous expanded polytetrafluoroethylene.

22. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 21 hours.

23. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 24 hours.

24. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 48 hours.

25 25. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 5 days.

30 26. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 10 days.

35 27. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an

increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 20 days.

28. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 30 days.

5 29. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 45 days.

10 30. An endoprosthesis assembly according to claim 21 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 60 days.

15 31. An endoprosthesis assembly according to claim 21 wherein the endoprosthesis is a self-expanding endoprosthesis.

20 32. An endoprosthesis assembly according to claim 31 wherein the delicate constraining sheath either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 21 hours.

25 33. An endoprosthesis assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 24 hours.

34. An endoprosthesis assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 48 hours.

30 35. An endoprosthesis assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 5 days.

35 36. An endoprosthesis assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprosthesis assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 10 days.

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37. An endoprostheses assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprostheses assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 20 days.

5 38. An endoprostheses assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprostheses assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 30 days.

10 39. An endoprostheses assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprostheses assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 45 days.

15 40. An endoprostheses assembly according to claim 31 wherein the delicate constraining sheath, in the absence of the packaging sheath, either at least partially disrupts or allows an increase in a maximum diameter of the endoprostheses assembly of at least 0.15mm, when exposed to a temperature of at least 60°C for a time of at least 60 days.

20 41. An endoprostheses assembly comprising an implantable endoprostheses capable of being diametrically expanded from a smaller diameter to a larger diameter; and a generally tubular, delicate constraining sheath provided coaxially around the endoprostheses at the smaller diameter of the endoprostheses, said constraining sheath being provided with means for disruption initiated by application of a distending force to the constraining sheath, wherein said assembly is stored at a temperature of less than about 5°C for at least 30 days.

25 42. An endoprostheses assembly according to claim 41 wherein the assembly is stored at a temperature of less than about 5°C for at least 60 days.

30 43. An endoprostheses assembly comprising a catheter balloon having a working length, an implantable endoprostheses having a length and capable of being diametrically expanded from a smaller diameter to a larger diameter; said endoprostheses being fitted coaxially over the catheter balloon with the length of the endoprostheses approximately centered axially over the working length of the catheter balloon, and a generally tubular constraining sheath provided coaxially around the endoprostheses at the smaller diameter of the endoprostheses, wherein the working length of the catheter balloon is less than the length of the endoprostheses.

35 44. An endoprostheses assembly according to claim 43 wherein the working length of the balloon is about 90 percent of the length of the endoprostheses or less.

45. An endoprosthesis assembly according to claim 43 wherein the working length of the balloon is about 80 percent of the length of the endoprosthesis or less.

46. An endoprosthesis assembly according to claim 43 wherein the working length of the balloon is about 70 percent of the length of the endoprosthesis or less.

5 47. An endoprosthesis assembly according to claim 43 wherein the working length of the balloon is about 60 percent of the length of the endoprosthesis or less.

48. An endoprosthesis assembly according to claim 43 wherein the working length of the balloon is about 50 percent of the length of the endoprosthesis or less.